REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

Substance of Interview

At the outset, Applicants wish to thank Examiner Negin for the courtesy of the telephonic interview held earlier today. Prior to the telephonic interview, the undersigned sent Examiner Negin the attached email outlining proposed changes to the claims to address the § 101 rejection.

As discussed in greater detail below, the proposed changes to the claims (1) change the preamble of the method from "a method of controlling a computer-controlled dosage device for the controlled dosage of a medicament into a body of a patient" to "a method of *administering a medicament* into a body of a patient * * * with the aid of a computer-controlled dosage device"; and (2) add to step (d) the active step of *"administering said medicament to said patient* using said dosage device." Thus, the thrust has shifted to administering the medicament to a patient using the dosage device, thereby, transforming the patient.

Examiner Negin indicated that an amendment along these lines should be acceptable and overcome the § 101 rejection due to the transformation.

Claim Amendments

As alluded to above, claim 1 has been amended to specify that the method is one for administering the medicament into the body of a patient with the aid of a computer-controlled

dosage device. Such amendment has clear support throughout the entire disclosure, as the entire description relates to computer-controlling the dosage device for just such purpose, and original claim 10 required monitoring the success "of the therapy," clearly indicating that a therapeutic purpose was at the root of the claims. Claim 1 has also been amended in step c) to specify the logical result of the original step wording, i.e, the provision of "an adapted dosage time profile." Claim 1 has then been amended in step d) to delete the reference to "the result of step c)" and instead to refer to the adapted dosage time profile.

Purely editorial amendments are made to claims 2, 3 and 10.

Applicants do not believe that any of the amendments introduce new matter. An early notice to that effect is earnestly solicited.

Substantive Issues

Claims 1-10 were rejected under 35 USC § 112, second paragraph, as being indefinite. In response, Applicants have amended the claims in a manner that Applicants believe overcomes the Examiner's concern. Specifically, as noted above, claim 1 has been amended in step d) to delete the reference to "the result."

Claims 1-10 were rejected under 35 USC § 101 as claiming non-statutory subject matter. In response, Applicants have amended claim 1, as indicated above, to specify the method to a method of administering a medicament into a body of a patient with the aid of a computer-controlled dosage device. Steps a)-c) lead to an adapted dosage time profile that is outputted to the dosage device in step d) and that controls the dosage device to administer the medicament. The method of claim 1 not only transforms the dosage device into a device of practical

therapeutic usefulness, but also transforms the human body when the transformed dosage device is used to administer the transforming medicament to the patient.

Claims 1-4 and 7-10 were rejected under 35 USC § 103(a) as being obvious over Christopherson et al. ("Christopherson"), US 5,944,680, in view of Winokur et al. ("Winokur"), US 5,968,932, in view of Higenbottam et al. ("Higenbottam"), WO 00/01434, in view of Willmann et al. ("Willmann"), *Biosilico, 1:* 121-124 (2003). In response, Applicants respectfully submit that the combination of Christopherson, Winokur, Higenbottam and Willmann fails to make out a *prima facie* case of the obviousness of any of the rejected claims. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

An element of the present method is that the administering of the medicament dose is as a function of time and is controlled.

The Examiner alleges that a person skilled in the art would have been motivated to modify Christopherson's ***implanted*** device so that, instead of applying voltages, apparently the device would administer the drug Montirelin™, as taught by Winokur. Not only is there no teaching or suggestion in the combination of such references how such a change in the principle of operation of Christopherson's device would or could be successfully accomplished, but Winokur teaches that Montirelin™ is administered as a ***single*** bolus injection just before bedtime. See, Winokur at column 7, lines 32-34 ("In practice, Montirelin may be administered as a bolus from 0 to 12 hours, preferably from 0.2 to 6 hours, prior to a normal sleeping period.") Thus, there's no teaching or suggestion in the combination that controlled administration of Montirelin™ would have been advantageous. Consequently, even if Christopherson's device

could have been modified, there's no good reason in the combination of references why a person skilled in the art would have been motivated to make the modification. *See, for example, In re Regel et al.,* 188 USPQ 136, 139, footnote 5 (CCPA 1975) ("The mere fact that it is *possible* to find two isolated disclosures which might be combined in such a way to produce a new compound does not necessarily render such production obvious unless the art also contains something to suggest the desirability of the proposed combination.")

In view of the foregoing, Applicants respectfully submit that the combination of Christopherson, Winokur, Higenbottam and Willmann does not make out a *prima facie* case of the obviousness of any of the rejected claims. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Claim 5 was rejected under 35 USC § 103(a) as being obvious over Christopherson in view of Winokur in view of Higenbottam in view of Willmann, and further in view of Sugita et al. ("Sugita"), US 2003/0175350. In response, Applicants respectfully submit that this rejection was dependent upon the combination of Christopherson, Winokur, Higenbottam and Willmann rendering *prima facie* the broad aspects of the present invention as embodied in main claim 1. Since it has been shown above that this is not, in fact, the case, Applicants respectfully submit that this rejection also should be reconsidered and withdrawn. Indeed, nothing in Sugita overcomes the above-noted defects in Christopherson, Winokur, Higenbottam and Willmann. Accordingly, the combination of Christopherson, Winokur, Higenbottam, Willmann and Sugita likewise fails to make out a *prima facie* case of the obviousness of claim 5.

Claim 6 was rejected under 35 USC § 103(a) as being obvious over Christopherson in view of Winokur in view of Higenbottam in view of Willmann, and further in view of the

definition of "numerical modeling" in *The Dictionary of Physical Geography* (2000). In response, Applicants respectfully submit that this rejection was dependent upon the combination of Christopherson, Winokur, Higenbottam and Willmann rendering *prima facie* the broad aspects of the present invention as embodied in main claim 1. Since it has been shown above that this is not, in fact, the case, Applicants respectfully submit that this rejection also should be reconsidered and withdrawn. Indeed, nothing in *The Dictionary of Physical Geography* overcomes the above-noted defects in Christopherson, Winokur, Higenbottam and Willmann. Accordingly, the combination of Christopherson, Winokur, Higenbottam, Willmann and *The Dictionary of Physical Geography* likewise fails to make out a *prima facie* case of the obviousness of claim 6.

Claims 1, 2, 5, 6, 9 and 10 were provisionally rejected on the ground of obviousness-type double patenting as being unpatentable over claims 2-7 of copending application Serial No. 11/917,452. In response, Applicants submit a terminal disclaimer relative to the copending application.

Claims 1, 2 and 6 were provisionally rejected on the ground of obviousness-type double patenting as being unpatentable over claims 11, 12 and 16 of copending application Serial No. 11/569,449. In response, Applicants submit a terminal disclaimer relative to the copending application.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,
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